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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,475	05/31/2001	Monika Lusky	017753-146	7808
21839	7590	12/24/2003	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MARVICH, MARIA	
POST OFFICE BOX 1404			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22313-1404			1636	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/867,475

Applicant(s)

LUSKY ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 6-37 is/are pending in the application.
- 4a) Of the above claim(s) 31, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-30, 32, 33, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/463,486.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

This office action is in response to an after-final amendment filed 11/24/03. **The amendment has been entered.** Claims 2, 3 and 5 are cancelled. Claims 1, 30 and 32 have been amended. Claims 1, 3-4, 6-37 are pending. Claims 31 and 34-35 are withdrawn. Upon further review of the instant claims and specification it is apparent that the application is not in condition for allowance. Therefore, prosecution is reopened. As new grounds of rejection are presented in this action that are not necessitated by applicant's amendment of the claims, this action is **Non-Final**.

#### *Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### *Claim Objections*

Claim 1 is objected to because of the following informalities: "a" which precedes encapsidation should be "an". Claim 12, line 2 "helper" is misspelled. In claim 19, line 4, 5' ITR is written ITR 5'. In claim 12, line 7, 3' ITR is written ITR 3'. In claim 21 an "or" appears after "vector is" and before "obtained". Claim 23 recites that the cell line is complementing whereas it should recite that the cell line complements the functions. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the term, "genomes of (i) and (ii) comprising" ITRs, encapsidation region and genes of early and late are unclear. It is unclear whether each genome individually comprises each of the listed components or collectively the genomes comprise these components.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "is in said first cell line" are unclear. It is unclear whether the first and second helper virus or just the first helper virus are in the cell line.

Claim 1 recites the limitation in step a "said first adenovirus" and "said second adenovirus" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "said first and/or second adenoviral vector" in claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 7 and 8 recite the limitation "said first helper adenovirus" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is vague and indefinite in that the metes and bounds of the phrase "in at least the gene encoding DBP, Pol and/or pTP" are unclear. Due to the linkage of the genes by "and", it is unclear how it can be a gene.

Claim 13 recites the limitation "said second adenoviral vector" in claim 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 and 23 are vague and indefinite in that the metes and bounds of the phrase "said first or second or first and second" are unclear. It would be remedial to recite, "selected from the group consisting of the first helper vector, the second helper vector or the first and second helper vector".

Claim 28 recite the limitation " said first or second or first and second " in claim 20. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recite the limitation "amplification step" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 is vague and indefinite in that the metes and bounds of the phrase "fresh second adenoviral helper vector" are unclear. It is unclear what is meant by use of the word "fresh".

Claim 36 is vague and indefinite in that the metes and bounds of the phrase "the method of claim 1(b)" are unclear. 1(b) is a step in the method of claim 1 and not a method unto itself.

### *Conclusion*

Claims 1, 3-4, 6-37 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

December 17, 2003

  
**REMY YUCEL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

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